

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

In re: PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL No. 1456
LITIGATION) Civil Action No. 01-12257-PBS
)
) Subcategory No. 06-11337-PBS
THIS DOCUMENT RELATES TO:)
) Hon. Patti B. Saris
)
*United States of America ex rel. Ven-a-Care of)
the Florida Keys, Inc. v. Dey, Inc., et al., Civil)
Action No. 05-11084-PBS)*

**PLAINTIFFS' REPLY TO DEY'S RESPONSE TO THE UNITED STATES'
LOCAL RULE 56.1 STATEMENT OF UNDISPUTED FACTS**

The United States respectfully replies to the Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Individual Local Rule 56.1 Statement in Opposition to the United States' Local Rule 56.1 Statement of Undisputed Material Facts as to Dey (MD #6432, Sub. #411) (hereinafter "Dey 56.1 Response" or "Dey-Opp-SOF").

Nothing in Dey's 56.1 Response creates a genuine dispute of material fact. Throughout its Response, Dey engages in argument and explications of its legal positions in situations wholly unresponsive to the statements of fact to which Dey is required to respond. As such, Dey's Response should be given short shrift by this Court. Rather than go through Dey's 56.1 Response adding yet a third statement at every numbered paragraph, the United States here only replies to specific responses where it believes a reply is of assistance in showing there is no genuine dispute as to the fact asserted in the first instance by the United States. No further reply is appropriate or required under Local Rule 56.1, and no facts are deemed admitted or positions otherwise conceded by reason of a party's silence in response to any particular response to a Rule 56.1 statement of undisputed fact submitted in support of a motion for summary judgment.

Further responsive argument to Dey's 56.1 Response is set forth in the United States' Reply to Dey's Opposition to Plaintiff's Motion for Summary Judgment, filed today.

The United States herein replies to Dey's Responses to the following Rule 56.1 statements of facts.

38. Virtually all indirect sales are at prices that are lower than Dey's WAC invoice price to the wholesaler. (Henderson Ex. 10, at 104:19-105:10) The wholesaler agrees to honor the contract price. (Henderson Ex. 10, at 106:20-107:3) Because the price paid by the indirect customer is less than the WAC invoice price from Dey to the wholesaler, Dey pays the wholesaler a "chargeback" to make the wholesaler whole. (Henderson Ex. 10, at 105) The chargeback on an indirect sale is typically the difference between the indirect contract price and the WAC on the invoice to the wholesaler.

In its Response to this statement of fact, Dey spends over five pages setting forth its own "statement" concerning wholesaler prices, upcharges and the meaning of WAC wholly unrelated to the specific facts set forth in the United States' statement. The Response should be disregarded in its entirety, but for the following admission of the specific facts set forth in SOF # 38, buried on pages 15 and 16 of Dey's response:

WAC is also used to determine the chargebacks Dey pays to a wholesaler when the wholesaler services Dey's indirect customers that have contracts with Dey. Retail customers, like pharmacies, may negotiate with Dey to purchase Dey's products at prices lower than WAC. . . . The Wholesaler then charges Dey for the difference between the WAC and the contract price, which is called a chargeback.

(Dey-Opp-SOF # 38, pp. 15, 16) (citations omitted).)

58. When Dey launched a drug, it reported its internally determined AWPs and WACs for drugs to certain publishers and data services, including First Data Bank ("FDB") (which maintains the National Drug Data File), Medi-Span, and Red Book (the "Publishers"). (Henderson Ex. 19A (Dey Answers to Interrogatories, Response No. 1); Dey-SOF ¶ 76.)

Dey purports to dispute this in its response, but in its sworn answers to interrogatories,

Dey said the following:

When Dey launched a drug, it reported its internally determined AWPs and WACs for drugs to certain publishers and data services, including: CliniDATA Source, Inc., Facts and Comparisons, First Data Bank (which maintains the National Drug Data File), Medical Data Institute, Medi-Span, Multum Information Sys / IQ Health, and Red Book (the “Publishers”).

(Henderson Ex. 19A (Dey Answers to Interrogatories, Response No. 1).)

59. After the launch of a drug, Dey periodically reported its AWPs and WACs to the Publishers. Dey reported prices to the Publishers when there was a price change. (Dey Answers to Interrog., Response No. 1; (Henderson Ex. 20, at 104.)

Dey purports to dispute this in its response, but in its sworn answers to interrogatories,

Dey said the following:

Dey periodically reported its AWPs and WACs to the Publishers subsequent to the launch of the drug and refers Plaintiffs to its price notification letters for the occasions on which this occurred.

(Henderson Ex. 19A (Dey Answers to Interrogatories, Response No. 1).)

Additionally, Todd Galles, the Dey employee who reported prices to the pricing compendia during a portion of the time relevant to this action, testified at deposition as follows:

Q. (BY MR. THOMAS) How frequently did Dey report prices to First DataBank?

MS. GIULIANA: Object to the form.

A. Whenever there was a price change.

(Henderson Ex. 20, at 104:9-12.)

60. Dey expected that the WACs and AWPs that it reported to First DataBank and the Red Book would be the WACs and AWPs that First DataBank and the Red Book would publish. (Henderson Ex. 21, at 467:19-467:22; Henderson Ex. 10, at 71.)

Dey says it disputes this in its response, but at the deposition of Dey, Inc. and Dey, L.P. through their corporate designee Pamela Marrs, Dey testified as follows:

Q. Dey did expect, though, that the AWPs that it reported to First DataBank and Red Book would be the AWPs that those companies published?

A. Yes.

(Henderson Ex. 21, at 467:19-467:22.)

Additionally, Russell Johnston, the Dey employee who reported prices to the pricing compendia during a portion of the time relevant to this action, testified at deposition as follows:

Q. Is – When your organization reports an AWP price to First DataBank do you expect that First DataBank will publish that figure as the published AWP?

MR. DOYLE: Objection as to form.

A. It's my experience when I have seen the published AWPs and WAC prices, in that they do match what we have generally reported, it would be my expectation that they would be, yes.

(Henderson Ex. 21, at 467:19-467:22.)

61. Dey continues to report WAC and AWP to FDB. (Henderson Ex. 22, at 303-304; Henderson Ex. 23, at 84.)

Dey disputes this in its response, but at the deposition of Dey, Inc. through its corporate designee Pamela Marrs on November 14, 2007, Dey testified as follows:

Q. MR. WINGET-HERNANDEZ: We've been talking -- we talked part of the day yesterday about the fact that Dey reports WAC's and AWP's to First DataBank, didn't we?

A. Yes, Dey does report WAC's and AWP's to First DataBank.

(Henderson Ex. 22, at 303:18-304:1.)

63. Dey supplies WAC and AWP to FDB because State Medicaid programs use it as a reference guide for pricing in the industry. (Henderson Ex. 24, at 299-300.)

Dey disputes this in its response, but at the deposition of Robert Mozak, Dey's Executive Vice President of Sales and Marketing, Mr. Mozak testified as follows:

Q. You're the Executive Vice-President for Sales and Marketing of Dey Laboratories, correct, Sir?

A. Uh-huh.

Q. And it's your testimony and you're telling the court and the jury that you don't know of any reason whatsoever that Dey Laboratories supplies its WAC prices to First Data Bank except that it's always done so. Is that your testimony?

A. Well, I also believe now that it is also utilized by the state as a reference guide; so that would be another reason to submit it.

Q. By the state Medicaid programs?

A. Yes.

Q. Reference guide for what?

A. For pricing in the industry.

(Henderson Ex. 24, at 299:18-300:7.)

68. On May 30, 1995, Dey reported to First DataBank WAC prices for its Albuterol Sulfate Unit Dose Solution, 0.083%, 3ml, as follows:

<u>NDC</u>	<u>PRODUCT DESCRIPTION</u>	<u>SIZE</u>	<u>UNITS PER CARTON</u>	<u>AWP</u>	<u>WAC</u>
49502-697-03	Albuterol Sulfate Inhalation Solution 0.083%	3 mL	25	\$30.25	\$24.75
49502-697-33	Albuterol Sulfate Inhalation Solution 0.083%	3 mL	30	\$36.30	\$29.70
49502-697-60	Albuterol Sulfate Inhalation	3 mL	60	\$72.60	\$59.40

(Henderson Ex. 31; Henderson Ex. 32, at FDB00918.)

Here again, in its Response to this statement of fact, Dey does not deny or contradict this statement, but instead spends over three pages setting forth its own “statement” concerning the reasons that it reported these WAC prices, the background discussions that took place, the fate of Ms. Burnham, who reported the change, and Dey’s subsequent changes to the AWPs and WACs for the same products. Such a discourse is wholly inappropriate in response to a 56.1 statement of undisputed fact and should be stricken in its entirety.

81. Before the launch of Dey’s Albuterol Sulfate Unit Dose product, NDC 49502-697-03, Dey’s Vice President of Sales and Marketing, Robert Mozak, sent a memorandum dated February 24, 1992, to Pamela Marrs, Charles Rice, and Jean-Pierre Termier, setting forth the proposed pricing for Dey’s new product, Albuterol Sulfate Inhalation Solution, in the unit dose form, NDC 49502-697-03. Pamela Marrs was and is the Chief Financial Officer; Charles Rice was the Chief Operating Officer and became President and CEO in the summer of 1992 (Henderson Ex. 34, at 341); and Jean-Pierre Termier was the President at the time. The memorandum includes an attachment which describes Dey’s pricing strategy for the drug, The attachment shows a proposed AWP for the Dey product

of \$32.30. In the attachment, in bullet-points, one of Dey's three "pricing objectives" was to:

PROVIDE AN INCENTIVE TO RETAIL AND CHAIN PHARMACIES TO PURCHASE DEY'S ALBUTEROL UNIT DOSE BY INCREASING THE SPREAD ON MEDICARE/MEDICAID REIMBURSEMENTS.

(Henderson Ex. 35.) There follows a description of Dey's "pricing strategies," with the first two bullets stating:

- 1) INCREASE THE SPREAD TO RETAIL/HOMECARE ACCOUNTS BY LOWERING ACQUISITION COST MORE THAN AWP
- 2) PHARMACY CHAIN BID RANGE: \$23.95 - \$26.50 (AVG. \$25.95) WILL INCREASE SPREAD FOR RETAIL AND PROVIDE DEY WITH HIGHEST PROFIT

Here again, in its Response to this statement of fact, Dey spends over four pages setting forth its own "statement," launching off on a brief-like defense of the efficacy of its Albuterol Sulfate product, the necessity of setting generic AWP's and WAC's below the reported prices for brand products, and even stating that "Dey did not manipulate its AWP upwards to create an artificial spread" – wholly ignoring the fact that it set its AWP high and thereafter declined to lower the AWP for its products as prices fell, thereby manipulating the spread. (Dey-Opp-SOF # 81, p. 53.) Dey does not deny any aspect of SOF # 81, and its response thereto should be disregarded in its entirety.

178. Dey did not contact any State Medicaid agencies or federal Medicaid officials to find out if it was appropriate to report inflated prices. (Henderson Ex. 10, at 28-29.)

AND

179. Dey never contacted any Medicare carrier to ask whether it was possible to report and cause to be published average wholesale prices that were higher than actual market prices. (*Id.*, at p. 28.)

Dey does not dispute these statements and offers no evidence that it ever contacted state or federal Medicaid officials or Medicare carriers to ask such questions. Instead, in response to both of these SOFs, Dey references notification letters that it alleges it sent to state Medicaid Administrators and Medicare Durable Medical Equipment Regional Carriers. Such letters do not disclose Dey's truthful AWP's and WAC's and so provide no guidance to the states or carriers, and, of course, do not ask for guidance or permission to report inflated prices, and so do not constitute evidence contrary to SOF's # 178 and 179.

Additionally, in response to SOFs 54 through 57 and 72 through 80, Dey purports to dispute certain aspects of the Declaration of the United States' expert Simon D. Platt, CPA (Henderson Ex. 19), who calculated Dey's average sales prices for the Subject Drugs, aggregating the sales transaction data on a quarterly basis net of chargebacks, discounts and rebates, and thereby calculated net average sales prices for Dey's direct and indirect sales. In these calculations, Mr. Platt utilized Dey's own transactional data. He then compared Dey's average net sales prices to the AWPs and WACs reported by First Databank and Red Book, and calculated the spreads on Dey's drugs.

Dey does not dispute Mr. Platt's calculations except to the wholly unspecified extent that such calculations conflict with Dey's own calculations of its gross sales, total chargebacks and other figures set forth in monthly sales reports and other reports generated by Dey's finance department. (Dey-Opp-SOF ¶¶ 54, 55, 56 and 57.) The exhibits upon which Dey relies in support of these responses consist of hundreds of pages of financial reports collected from Dey's

finance department, yet Dey fails to point to a *single figure* within those hundreds of pages of data that contradicts the figures from Dey's own transactional and chargeback databases used by Mr. Platt in his calculations. A simple denial in the absence of evidentiary support does not form a basis for a genuine dispute under Local Rule 56.1, and Dey's denials concerning Mr. Platt's calculations should be given short shrift by this Court.

Aside from filing hundreds of pages of financial reports and suggesting that some numbers therein might, potentially, differ from Mr. Platt's calculations, Dey's only other approach to Mr. Platt's report is to point out what he did *not* do. Thus, in response to SOF ¶ 72, Dey suggests that Mr. Platt's calculations do not reflect the average wholesale price because he did not examine wholesaler data; and, in support of this proposition, Dey provides a quote from Mr. Platt's deposition in which Mr. Platt states "in principle there could be some elements of the calculations you outline best obtained from the wholesalers' records." (Dey-Opp-SOF ¶ 72.) The portion of Mr. Platt's deposition testimony quoted by Dey is misleading, however, because Dey fails to include Mr. Platt's testimony that follows on the very same page of the transcript:

Q. In order to determine that average wholesale price, as I've just described it, would the best place to get accurate information for that is to go to the wholesalers and get their data as to what on average they sold to providers?

A. Potentially, or frankly potentially going to the providers and finding out what they paid.

Q. Okay.

A. Again, we're in this -- in your hypothetical world here. Recognizing from the Dey data that in the aggregate Dey is selling 2.4 -- for this period for these NDCs is selling \$2.4 billion worth of drugs, we know from the data that a billion dollars is going to other than wholesalers, presumably

providers. Out of the remaining 1.4 billion, that is, that's going to wholesalers, from that which is reported from the wholesalers back to Dey, we have records accounting for, dealing with 1.3 billion of that 1.4. So to extend your hypothetical slightly further, if Dey is responsible for that reporting, and based on the records it has available to it without going to those third parties in some other way, it can account for roughly 95 percent, can understand, has insight into what providers are paying for 95 percent of its sales dollars.

(3/18/09 Platt Dep., 235:12-236:15, attached as Exhibit A hereto.) Thus, Mr. Platt concluded that the use of Dey's transactional and chargeback databases provides a calculation of the average wholesale prices of Dey's drugs to within an accuracy of 95%. Dey has pointed to no data or testimony to refute this conclusion in its response to the United States' statement of fact, and so Mr. Platt's calculations should be considered undisputed.

Elsewhere, in its responses to SOFs ¶¶ 74 through 80, Dey complains that, because the numbers that Mr. Platt calculated are, in fact, averages, they do not reflect the true "prices at which Dey sold those products to its indirect customers" or the "prices generally and currently paid by wholesalers who purchased the drugs from Dey." Here, though, Dey is merely observing the obvious fact that, because the numbers that Mr. Platt calculated are averages, some providers pay more for the drugs, and some pay less. This does not constitute a genuine dispute with Mr. Platt's calculations or with his conclusion that Dey's reported AWPs and WACs reflect not its average prices but rather a substantial inflation of its average prices.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

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Dated: September 22, 2009